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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,155	01/24/2002	Mohammed S. Safadi	3940/1K137US1	3092

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EXAMINER

GEORGE, KONATA M

ART-UNIT

PAPER NUMBER

1616

DATE MAILED: 03/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/057,155

Applicant(s)

SAFADI ET AL.

Examiner

Konata M. George

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1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5,9</u> . | 6) <input type="checkbox"/> Other:  |

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### **DETAILED ACTION**

Claims 1-55 are pending in this application.

#### ***Information Disclosure Statement***

1. The information disclosure statements (IDS) submitted on April 25, 2002 and November 22, 2002 were noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statements.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aubert et al. (US 5,185,159) in view of Barry et al. (US 5,055,306).

Aubert discloses a pharmaceutical composition base on valproic acid and a process of preparing it. Column 1, lines 65-68 bridging col. 2, lines 1-20, describe a pharmaceutical composition available in France containing sodium valproate, calcium silicate, binders, wetting solvents, absorbent products and lubricants. It is the position of the examiner that although calcium silicate is classified by reference as an excipient the applicant refers to it as a non-hygroscopic additive (page 14, lines 16-21, specification). It is the position of the examiner that the water or isopropyl alcohol can be classified as non-polymeric carriers and the binders and lubricants can be excipients.

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Table D, col. 6, lines 18-45, describe a coated tablet and the final tablet weighing 567 mg/unit and corresponding to 500 mg of sodium valproate, which is approximately 88% of the tablet. The prior art does not teach the carrier as carbomer.

Barry discloses a sustained-release formulation comprising a pharmacologically active substance and one preferably one or more excipients and a coating covering the core (abstract). The excipients may contain excipients such as a carbomer (col. 6, lines 10-18). Column 7, lines 3-46, specifically on lines 27-28, describes anti-epileptic drugs such as sodium valproate. Example 3 in column 11, teaches a granule containing a carbomer and nifedipine, it is the position of the examiner that although nifedipine is used as the drug in the example any drug can be used.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use modify in the composition of Aubert to contain a carbomer in view of the teachings of Barry. Barry discloses the use of a carbomer in a composition containing a drug, which may be sodium valproate. Aubert discloses the usage of excipients along with sodium valproate in a drug preparation and since carbomer is known in the pharmaceutical arts as a carrier it would have been obvious to use a carbomer in the composition to develop the claimed invention.

### ***Conclusion***

3. Claims 1-55 stand rejected.

### ***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is

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(703) 308-4646. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached at (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Konata M. George

  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER